

ROQUETTE MAGNESIUM STEARATE LS

Definition

Product Identifier

Product name: ROQUETTE MAGNESIUM STEARATE LS

Compound of magnesium with a mixture of solid organic acids.

Specifications

A) CHARACTERS

APPEARANCE Very fine, light-white powder.

B) IDENTIFICATION

IDENTIFICATION TESTS Complies.

C) TESTS

MAGNESIUM CONTENT (on DS)	4.0 - 5.0 %
LOSS ON DRYING	6.0 % max.
ACIDITY or ALKALINITY	Complies.
SPECIFIC SURFACE AREA	5.0 m ² /g max.
ACID VALUE	195 - 210
FREE FATTY ACID	1.0 % max.
RELATIVE CONTENT OF STEARIC ACID	40 % min.
RELATIVE CONTENT OF STEARIC AND PALMITIC ACID	90 % min.
CHLORIDES	0.10 % max.
SULFATE	1 % max.
CADMIUM	3 mg/kg max.
LEAD	10 mg/kg max.
NICKEL	5 mg/kg max.
PARTICLE SIZE (SIEVE):	
- RESIDUE ON 45 MICRONS	1.0 % max.
MICROBIOLOGICAL VALUES:	
- TOTAL AEROBIC MICROBIAL COUNT	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	100 CFU/g max.
- ESCHERICHIA COLI	Not detected in 1g

PRODUCT SPECIFICATIONS SHEET

ROQUETTE MAGNESIUM STEARATE LS

- PSEUDOMONAS AERUGINOSA	Not detected in 1g
- SALMONELLA	Not detected in 10g
- STAPHYLOCOCCUS AUREUS	Not detected in 1g

Indicatives Values

Solubility information:

Insoluble in alcohol, water and ether.

Comments

Not intended for use in manufacture of parenteral dosage forms.

Methods used by ROQUETTE may be pharmacopeia methods or alternative validated methods which have been compared to the pharmacopeia methods.

Conformity

Conforms to the requirements of the current monograph

- European Pharmacopoeia MAGNESIUM STEARATE (0229)
- National Formulary from USP-NF MAGNESIUM STEARATE
- Japanese Pharmacopoeia MAGNESIUM STEARATE

Please contact us for any statement regarding compliance to the general chapter (elemental impurities, residual solvent, organic volatile impurities, metal catalyst, metal reagent).

Storage

Retest date manufacturing date + 48 months.

We recommend to preserve the product in its unopened original packaging, preferably protected from wide variations of temperature and humidity. Upon opening, use the product as quickly as possible to prevent moisture regain.

Disclaimer

The information provided in this Product Specification Sheet relates only to the specific product designated and may not be applicable when such product is used in combination with other materials or in any process.

All information and instructions provided in this Product Specification Sheet are based on the current state of our knowledge at the latest revision date indicated. It is the responsibility of the user to be aware of and to follow the regulations applying to our product for its possession, handling and use.

Notes : All the dates are formatted like YYYY/MM/DD.